

Psychological consequences of solid organ transplantation. A study among Dutch liver transplant recipients

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This study will focus on the positive and negative psychological consequences of organ transplantation in Dutch organ transplant recipients. The study will describe on posttraumatic stress and posttraumatic growth after organ transplantation, their...

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|------------------------------|-------------------------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Hepatic and hepatobiliary disorders |
| Study type | Observational non invasive |

Summary

ID

NL-OMON38250

Source

ToetsingOnline

Brief title

Psychological consequences of organ transplantation

Condition

- Hepatic and hepatobiliary disorders
- Hepatobiliary therapeutic procedures

Synonym

liver transplantation, organ failure

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Organ transplantation, Post traumatic growth, Post traumatic stress, Psychological consequences

Outcome measures

Primary outcome

- 1 Post traumatic stress
- 2 Post traumatic growth

Secondary outcome

- 1 Demographic characteristics
- 2 Coping
- 3 Mastery
- 4 Self efficacy
- 5 Prior psychopathology
- 6 Social support
- 7 Transplant related characteristics
- 7 Health related Quality of life
- 8 Psychological health
- 9 Adherence
- 10 Mortality
- 11 Morbidity: infection en rejection

Study description

Background summary

Organ transplantation has become the treatment of choice for a number of

life-threatening illnesses. As the clinical outcomes and survival of organ transplantation improve, other outcomes such as health related quality of life and psychosocial consequences of transplantation become increasingly important targets of evaluation. Generally, health related quality of life improves after transplantation but, especially psychological health, does not restore to the level in the general population. Recent studies show that 40-55% of transplant recipients experience stress even years after the transplantation. About 12% experience high levels of stress, which may lead to poorer psychological health and poorer adjustment to transplantation. To understand the impact of medical illnesses on people's lives the application of a trauma model can be informative. Transplantation is a life changing, life threatening and potential life ending experience, which can be felt as traumatic. This traumatic experience may have negative as well as positive consequences for the psychological health of transplant recipients. Negative consequences include: anxiety, depression and post traumatic stress (PTS). Positive consequences can be beneficial psychological adjustment and post traumatic growth (PTG). So far, 3 studies have been performed on PTS in organ transplant recipients. These studies show that 5-17% of transplant recipients meet the criteria for Post Traumatic Stress Disorder (PTSD), and another 5-17% of transplant recipients are diagnosed with sub threshold PTSD. Though, numerous risk factors of PTSD, like personal characteristics, transplant related characteristics and characteristics of the consequences of transplantation, are mentioned in these studies, it is not clear what the most important risk factors are. Also, the impact of PTS on outcomes as quality of life, psychological health, adherence, mortality and morbidity are inconclusive. To our knowledge, no research has been performed on PTG after organ transplantation yet.

Study objective

This study will focus on the positive and negative psychological consequences of organ transplantation in Dutch organ transplant recipients. The study will describe on posttraumatic stress and posttraumatic growth after organ transplantation, their associated factors and impact on outcome variables.

Objectives of this study

1. To determine the prevalence of posttraumatic stress symptoms and post traumatic growth in Dutch solid organ transplant recipients.
2. To identify factors associated with posttraumatic stress symptoms and post traumatic growth in Dutch solid organ transplant recipients.
3. To determine the impact of posttraumatic stress symptoms and post traumatic growth PTSD on quality of life, psychological health, non compliance, mortality and morbidity in Dutch solid organ recipients.

With the results of the study counseling programs to prevent negative consequences of transplantation and to promote positive consequences of transplantation can be developed.

Study design

A prospective cohort study. Liver transplant recipients will be followed before transplantation (waiting list period) and in the first two years after transplantation. Data assessment, by questionnaire, will be done before transplantation and 3, 6, 12 and 24 months after transplantation. Transplant related characteristics, mortality and morbidity after transplantation will be assessed by medical record review.

Study burden and risks

No serious adverse events should be expected. In case participants experience disadvantages due to participation in the research counseling will be offered by the department of Health Psychology of the UMCG.

Participants will be asked to fill in a questionnaire 5 times. The time needed to fill in the questionnaire varies between 35 en 60 minutes. Patient enlisted on the waiting list, if not yet transplanted, will receive a brief questionnaire every 6 months to update the pre transplant status of psychological health and quality of life. Time investment of this brief questionnaire is about 20 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

For UMCG: Patients enlisted on waitinglist for liver transplantation in September 2009, or placed on the waitinglist between October 2009 and October 2013.

For EMC and LUMC: Patients enlisted on waitinglist for liver transplantation in June 2011, or placed on the waitinglist between July 2011 and October 2013.; Receiving pre- and post transplant care at the UMCG, EMC or LUMC.

Aged 18 years or older.

Exclusion criteria

No thorough command of the Dutch language

Severe cognitive dysfunctioning due to encephalopathie stage 3-4

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2009

Enrollment: 98

Type: Actual

Ethics review

Approved WMO

Date: 25-09-2009

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 10-06-2011

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 02-08-2012

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL28627.042.09 |